

Display Date	11-8-99
Publication Date	11-9-99
Certifier	M. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 19, 1999, 8 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Mary J. Cornelius, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194, ext. 118, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12523. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for an optical device intended to assist in the evaluation of colonic polyps using laser-induced autofluorescence.

Procedure: On November 19, 1999, from 8:30 a.m. to 1:30 p.m., and from 2 p.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views,

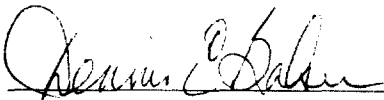
orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 15, 1999. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 15, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On November 19, 1999, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information regarding pending and future device issues (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this information.

FDA regrets that it was unable to publish this notice 15 days prior to the November 19, 1999, Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 10-29-99
October 29, 1999



Dennis E. Baker
Associate Commissioner for
Regulatory Affairs

[FR Doc. 9909???? Filed ??09??0999; 8:45 am]

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